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| 10/568,529 | 02/17/2006 | Charlotte Lindhardt | MERCK3133 | 5069 |
| 23599 7590 07/12/2010 MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@mwzb.com

Office Action Summary

Application No.

10/568,529

Applicant(s)

LINDHARDT ET AL.

Examiner

JAMESON Q. MA

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2010.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
4a) Of the above claim(s) 2-8 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1 and 9-25 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/22)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1, 10-13, 16-18, 20-21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schrecengost et al. (US 6,660,489) in view of Gaylarde et al. (Microbial Contamination of Stored Hydrocarbon Fuels and its Control), further in view of Grubbs et al. (US 4,945,144) or Friswell et al. (US 5,490,872) and Grubbs et al. (US 4,945,144).

Regarding claims 1, 10-13, 16-18, 20 and 23. Schrecengost discloses a method for detection and/or quantification of a hydrophilic compound (ATP) dispersed in a liquid matrix comprising:

providing a sample of a liquid (see C2/L49-50: biological sample)

adding to said sample an aqueous capture solution (see C3/L6-14) comprising an anionic surfactant (see C4/L22-25: SDS or sulfate ion), wherein said surfactant improves the yield of the hydrophilic compound extracted from the matrix

measuring the hydrophilic compound in the aqueous phase (see abstract).

Schrecengost discloses that the method for assaying for the presence of ATP in a sample involves allowing the ATP-magnesium-luciferin complex to interact with luciferase, wherein light is produced; and measuring the intensity of the light, wherein the presence of light corresponds to the presence of ATP (see C3/L6-24).

Schrecengost discloses that an anionic substance (for example, SDS) is used to neutralize the positive charge of the ATP extractant (see C4/L53-61). It is further noted that the reference need not disclose a neutral surfactant as recited in claim 21 because of the preceding recitation of 'optionally in combination with.'

The mixing of said sample and said capture solution thoroughly and allowing an aqueous phase to separate from the sample phase are inherent properties of a method wherein an extractant is mixed with a biological sample.

Schrecengost does not explicitly disclose the liquid as a hydrophobic matrix. However, the reference does disclose that *many industries* have a need for rapid microbial monitoring (see C1/L19-31).

Gaylarde discloses that microbial contamination is a major problem in the petroleum refining industry which can lead to a loss of product quality, formation of sludge and deterioration of pipework and storage tanks. Gaylarde discusses three major classes of fuel – gasoline, aviation kerosene and diesel (see abstract). Gasoline, aviation kerosene, and diesel are hydrophobic matrices.

It would have been obvious to one of ordinary skill in the art at the time of invention to use as the method of Schrecengost with gasoline, aviation kerosene or diesel as the tested product, as doing so would have resulted in nothing more than choosing from a finite number of identified and predictable solutions of products at-risk of microbial contamination, as disclosed by both Schrecengost and Gaylarde.

Modified Schrecengost does not explicitly disclose the capture solution containing a water soluble dye. However the reference does disclose that a cationic extractant such as benzalkonium chloride, benzethonium chloride, or dodecyl trimethyl ammonium chloride (see C4/L53-61).

Grubbs teaches the cationic extractant methylene blue (see C10/L49-50).

It would have been obvious to one of ordinary skill in the art at the time of invention to substitute for the disclosed cationic extractants of Schrecengost, with the cationic methylene blue as taught by Grubbs, because doing so would have resulted in nothing more than the simple substitution of known cationic extractants with a reasonable expectation of success.

Alternatively, Friswell teaches that Dyes and markers are needed to clearly distinguish chemically or physically similar liquids (see C1/L26-27). Schrecengost teaches many different permutations of chemically similar extractant solutions (see examples). Further, Grubbs teaches the dye methylene blue.

It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate a dye as taught by Friswell into the extractant solutions taught by modified Schrecengost, in order to distinguish the many types of chemically similar liquids. It would have further been obvious to incorporate methylene blue as the dye because doing so would have resulted in nothing more than choosing from a finite number of identified and predictable dye solutions.

For claim 20, it is viewed that the quantity of dye used in modified Schrecengost would be present in a concentration sufficient to allow good visibility of the aqueous phase.

3. Claims 9, 14, 19 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schrecengost et al. (US 6,660,489) in view of Gaylarde et al. (Microbial Contamination of Stored Hydrocarbon Fuels and its Control), further in view of Grubbs et al. (US 4,945,144) or Friswell et al. (US 5,490,872) and Grubbs et al. (US 4,945,144) as applied to claims 1, 10-13, 16-18, 20-21 and 23 above, and further in view of Calvo Salve et al. (US 5,843,509).

Regarding claims 9, 14 and 24, modified Schrecengost discloses all of the claim limitations as set forth above. Additionally, Schrecengost discloses that an anionic substance (for example, SDS) is used to neutralize the positive charge of the ATP extractant (see C4/L53-61). However, the reference does not explicitly disclose lecithin as an extractant.

SDS is a well-known anionic substance and surfactant (surface active agent).

Calvo Salve discloses that lecithin is a natural surfactant (C1/L24) and that it is anionic (see C2/L26).

It would have been obvious to one of ordinary skill in the art at the time of invention to substitute lecithin as taught by Calvo Salve, for SDS in the extractant mixture of modified Schrecengost, because doing so would have resulted in the simple substitution of known anionic surfactants capable of neutralizing a positive charge, with a reasonable expectation of success.

Regarding claim 19, modified Schrecengost discloses all of the claim limitations as set forth above, but the reference does not explicitly disclose the lecithin in an effective concentration between 0.1% (w/v) and 1% (w/v). Schrecengost does disclose that the purpose of the anionic substance is to effectively neutralize the negative effects of positively charged extractants commonly used to remove ATP from a biological sample (see C4/L22-27). As the effective neutralization of positively charged extractants is a variable that can be modified, among others, by adjusting said lecithin concentration, the precise lecithin concentration would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made. As such, without showing unexpected results, the claimed lecithin concentration cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the lecithin concentration in the method of modified Schrecengost to obtain the desired effective neutralization of the positively charged extractant (In re Boesch, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (In re Aller, 105 USPQ 223).

4. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schrecengost et al. (US 6,660,489) in view of Gaylarde et al. (Microbial Contamination of Stored Hydrocarbon Fuels and its Control), further in view of Grubbs et al. (US 4,945,144) or Friswell et al. (US 5,490,872) and Grubbs et al. (US 4,945,144) as applied

to claims 1, 10-13, 16-18, 20-21 and 23 above, and further in view of Lawrence et al. (US 2002/0197631).

Regarding claim 15, modified Schrecengost discloses all of the claim limitations as set forth above. The reference is directed to extracting ATP from a sample for measurement. The reference does not disclose the capture solution further comprising a phosphate buffer.

Lawrence discloses that a capture solution containing phosphate buffer promotes the dissolution of cellular material out of cells. Additionally, Lawrence discloses that the capture solution is compatible with detergents such as SDS (see [0107]).

It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate a phosphate buffer taught by Lawrence, into the extractant mixture/capture solution of modified Schrecengost, because doing so would promote the dissolution of cellular materials (including ATP) out of cells, which would enhance its detectability in a luciferase assay as disclosed by Schrecengost.

5. Claims 15 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schrecengost et al. (US 6,660,489) in view of Gaylarde et al. (Microbial Contamination of Stored Hydrocarbon Fuels and its Control), further in view of Grubbs et al. (US 4,945,144) or Friswell et al. (US 5,490,872) and Grubbs et al. (US 4,945,144) as applied to claims 1, 10-13, 16-18, 20-21 and 23 above, and further in view of Calvo Salve et al. (US 5,843,509), as applied to claims 9, 14, 19, and 24 above, further in view of Green et al. (abstract, Effect of chemical sanitizing agents on ATP bioluminescence measurements).

Regarding claims 15 and 22, modified Schrecengost discloses all of the claim limitations as set forth above. Schrecengost also discloses that sanitizers such as bleach are used in ATP bioluminescence assay methods and that these substances are known to have a negative affect on luciferase activity (see C2/L7-15 and C6/L4-22)

The reference does not explicitly that the sanitizer is sodium hypochlorite. However, sodium hypochlorite is a type of bleach. Further, Green discloses that sodium hypochlorite used in proper concentrations is a chemical sanitizing agent that does not affect ATP bioluminescence measurements (see abstract).

It would have been obvious to one of ordinary skill in the art at the time of invention to use sodium hypochlorite as the sanitizing agent in the method of modified Schrecengost because as evidenced by Green, sodium hypochlorite is a sanitizing agent that would not negatively affect ATP bioluminescence measurements. This avoids the drawbacks cited by Schrecengost of known sanitizing agents. Additionally, doing so would have resulted in nothing more than choosing from a finite number of identified and predictable bleach solutions, known to be compatible in ATP bioluminescence measurement assays.

Modified Schrecengost discloses all of the compounds claimed in claim 22. Regarding the specific amounts that are claimed, it is noted that these amounts would change based on the amount of sample to be analyzed, among other variables. These amounts therefore cannot be considered critical absent unexpected results as one of ordinary skill in the art at the time of invention would have optimized these amounts based on the amount of sample to be analyzed, among other variables.

6. Claims 1, 13, 17-18, 20-21, 23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundin et al. (US 5,705,345) in view of Schrecengost et al. (US 6,660,489), Gaylarde et al. (Microbial Contamination of Stored Hydrocarbon Fuels and its Control), and Friswell et al. (US 5,490,872).

Regarding claims 1, 13, 17-18, 20-21, 23 and 25 Lundin discloses a method for detection and/or quantification of a hydrophilic compound (ATP) dispersed in a liquid matrix comprising:

providing a sample of a liquid (see C7/L1-4: biological specimen)

adding to said sample an aqueous capture solution (see C7/L5-9) comprising an zwitterionic surfactant (see C8/L34-51), wherein said surfactant improves the yield of the hydrophilic compound extracted from the matrix

measuring the hydrophilic compound in the aqueous phase (see C1/L15-19: assaying by luciferase assay viewed as measuring).

It is further noted that the reference need not disclose a neutral surfactant as recited in claim 21 because of the preceding recitation of 'optionally in combination with.'

The mixing of said sample and said capture solution thoroughly and allowing an aqueous phase to separate from the sample phase are inherent properties of a method wherein an extractant is mixed with a biological sample.

Lundin does not explicitly disclose the liquid as a hydrophobic matrix.

As disclosed above, Schrecengost discloses a method for microbial monitoring where extracted ATP is used for microbial monitoring. However, the reference further

discloses that *many industries* have a need for rapid microbial monitoring (see C1/L19-31).

Gaylarde discloses that microbial contamination is a major problem in the petroleum refining industry which can lead to a loss of product quality, formation of sludge and deterioration of pipework and storage tanks. Gaylarde discusses three major classes of fuel – gasoline, aviation kerosene and diesel (see abstract). Gasoline, aviation kerosene, and diesel are hydrophobic matrices.

It would have been obvious to one of ordinary skill in the art at the time of invention to use as the method of Lundin with gasoline, aviation kerosene or diesel as the tested product in order to determine contamination levels in the petroleum refining industry, as disclosed by both Schrecengost and Gaylarde.

Modified Lundin does not explicitly disclose the capture solution containing a water soluble dye.

Friswell teaches that dyes and markers are needed to clearly distinguish chemically or physically similar liquids (see C1/L26-27). Lundin teaches many different permutations of chemically similar extractant solutions (see example 1).

It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate a dye as taught by Friswell into the extractant solutions taught by modified Lundin, in order to distinguish the many types of chemically similar liquids (permutations of extractant solutions) from each other.

Response to Arguments

7. Applicant's arguments filed 4/23/10 have been fully considered but they are not persuasive. Applicant argues on pages 6-7 of the response that because the references do not disclose the anionic substance, such as SDS, as an extractant and thus they do not teach the instant claim limitations. However, it is noted that the claim requires a capture solution containing the anionic substance generally, and applicant's designation of the substance as an extractant does not change the fact that the substance is present in the solution of the prior art. Applicant's arguments to newly added claim 25 have been addressed with a new rejection. Applicant argues on page 7 that an experiment in the instant specification shows that benzalkonium chloride surfactant mixtures are less suitable for extracting compounds from hydrophobic matrices. This does not address the combination of Gaylarde and Schrecengost as the references do not teach this. Additionally, even if they did, evidence of something that is less suitable does not negate the combination if it is at all suitable to the intended purpose. Additionally, since Gaylarde teaches that fuel supplies can be contaminated by microbes and Schrecengost teaches that ATP determination is a method for determining microbes, it is the examiner's position that a skilled artisan would select the method of Schrecengost to detect microbial contamination in oil as taught by Gaylarde. Schrecengost further provides motivation for combination in that it discloses that *many industries* have a need for microbial monitoring as set forth above.

Regarding applicant's argument to Grubbs, it is noted that Grubbs need not teach that methylene blue is an extractant. Grubbs' teaching of methylene blue still

teaches the cationic compound methylene blue. Therefore, the combination used wherein cationic substances are substituted has not been convincingly overcome. Applicant's argument that dyes are added for a different purpose in the instant method does not change the fact that the same material is present in the capture solution, as required by the instant claims.

Applicant provides no arguments to the combination which uses Friswell and Grubbs to teach the dye.

Applicant argues that Calvo Salve is directed to a different field and a skilled worker would not look towards Calvo Salve for guidance. However, as noted in the Office Action, Schrecengost discloses that an anionic substance (for example, SDS) is used to neutralize the positive charge of the ATP extractant (see C4/L53-61). SDS is a well-known anionic substance and surfactant (surface active agent).

Calvo Salve discloses that lecithin is a natural surfactant (C1/L24) and that it is anionic (see C2/L26).

Calvo Salve is used for its teaching of lecithin and its properties and thus is viewed to be pertinent to the instant rejections and claims.

Applicant provides no specific arguments to the teachings of Green and its subsequent combination.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMESON Q. MA whose telephone number is (571)270-7063. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Marcheschi can be reached on (571)272-1374. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JM
July 2, 2010

/Michael A Marcheschi/
Supervisory Patent Examiner, Art
Unit 1797